K040501

APR 2 9 2005

XI. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPRIETARY NAME: DBX® Demineralized Bone Matrix Putty
DBX® Demineralized Bone Matrix Paste
DBX® Demineralized Bone Matrix Mix

COMMON NAME: Bone Grafting Material, Synthetic

PROPOSED REGULATORY CLASS: Class II

PRODUCT CODE: LYC

PANEL CODE: 76 – Dental

SPONSOR: Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837
732-661-0202

INDICATIONS FOR USE:

DBX® Putty and Paste are intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral/maxillofacial and dental intraosseous defects including:

- Ridge augmentation
- Filling of extraction sites
- Craniofacial augmentation
- Mandibular reconstruction
- Filling of cystic defect
- Filling of lesions of periodontal origin
- Filling of defects of endodontic origin
- Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture
- Filling of resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall.

DBX® Mix is intended for mandibular reconstruction only.

DBX® is intended for single patient use only.

DEVICE DESCRIPTION:

DBX® is intended for single patient use only. DBX® Demineralized Bone Matrix is available in three forms: Paste, Putty and Mix. DBX® products are completely resorbable. DBX® Paste and Putty are composed of processed human cortical bone;

the DBX® Mix is composed of processed human corticocancellous bone. The bone granules are mixed with sodium hyaluronate ("NaHA") in varying combinations to form the DBX® Putty, Paste and Mix. All versions of DBX® are available in five sizes.

DBX® is osteoconductive and has been shown to have osteoinductivity potential in the athymic mouse model. It is unknown how the osteoinductivity potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

PREDICATE DEVICES:

DBX® is substantially equivalent to Geistlich-Pharma's Bio-Oss Anorganic Bovine Bone (K970321), Biomet's 3i Calcium Sodium Phosphate Bone Cement (K003493) and Xomed's Merogel (K001148).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2005

Ms. Kathleen M. Laffan
Regulatory Submission Specialist
Musculoskeletal Transplant Foundation
125 May Street, Suite 300
Edison Corporation Center
Edison, New Jersey 08837

Re: K040501
Trade/Device Name: DBX Demineralized Bone Matrix
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: NUN
Dated: March 18, 2005
Received: March 21, 2005

Dear Ms. Laffan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040501

IV. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040501

Device Name: DBX® Demineralized Bone Matrix

Indications for Use:

DBX® Demineralized Bone Matrix is intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral/maxillofacial and dental intraosseous defects including:

- Ridge augmentation
- Sinus lifts
- Craniofacial augmentation
- Filling of defects of endodontic origin
- Filling of cystic defects
- Filling of extraction sites
- Filling of lesions of periodontal origin
- Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fractures
- Filling resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall.

For dental applications, one or more of the product formulations, depending upon specific anatomical location and physician and/or dentist preference, can be placed in the dental intraosseous defect site.

DBX® is osteoconductive and has been shown to be osteoinductive in both validated animal models and a validated *in vitro* assay. DBX® has not been proven osteoinductive in a human model.

DBX® is intended for single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number CONFIDENTIAL K040501